

Exhibit B

*State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Laboratories, Inc., et al.*

Exhibit to Plaintiffs' Motion for Partial Summary Judgment

R-72-89

ADDENDUM TO THE FINAL STATEMENT OF REASONS

The following are the comments from the Office of Administrative Law and the Department's response:

1. The rulemaking file fails to provide adequate explanation and documentation as to why the EAC should be established at AWP-5%, and therefore fails to comply with Government Code section 11349.1.

DHS RESPONSE: The Department has added the following documentation and data to the rulemaking file to comply with the requirements of Government Code section 11349.1, and in response to concerns from the Office of Administrative Law regarding the documentation of AWP-5%:

Attachments B, D, and E below, were available in the original rulemaking file.

- o Attachment B - November 9, 1988 letter from John O'Hara
- o Attachment D - Statewide Survey of Pharmacy Practices
- o Attachment E - Paid Claims/Savings data, 1989

Attachments A, C, F, G, H, I, and J below, have been added to the rulemaking file and are now available for public review.

- o Attachment A - Governor's Exception Language to the 1989 Budget
- o Attachment C - State Medicaid Manual, Sections 3605 through 3605.3
- o Attachment F - July 19, 1989 Letter from Lawrence L. McDonough
- o Attachment G - October 1989 Associated News Clipping
- o Attachment H - Pharmacists' Payment Data-1987/88
- o Attachment I - Transmittal Notice from Region IV
- o Attachment J - September 22, 1989 Letter to Lawrence McDonough

2. The Final Statement of Reasons fails to include an adequate summary and response to public comments, and therefore, does not meet the requirements of Government Code section 11346.7, subdivision (b) (3).
 - A. The response to comments in section 3.d. does not directly focus on or show meaningful consideration of the comment, and is therefore inadequate.

DHS RESPONSE (3.d.): Discounting the dispensing fee may have been agreed to historically; however, current federal regulations at 42 C.F.R. section 447.332, require the Department to make drug reimbursements based on the estimated acquisition cost of the drug without including any loss on dispensing fee reimbursements. This regulation does not address the issue of the dispensing fee

reimbursement; therefore, the Department has determined that no posthearing change is required as a result of this comment.

B. The Department of Health Services does not include a summary response to testimony at section 9.o.

DHS RESPONSE (9.o.): This regulation is not inconsistent. Section 51513 (a) (8) refers to the various regulated payment methodologies. For products reimbursed at the direct price, FAC, or the MAIC, AWP-5% would not be applied; however, for all other drug products, AWP-5% would be applied as the payment level. This regulation is consistent with State statutes and federal requirements at 42 C.F.R. sections 447.331 and 447.332; therefore, the Department has made no posthearing changes as a result of this comment.

C. The response in section 9.j. is inadequate because it does not explain fully the rationale and specific legal authority for rejecting the recommendation as required in Government Code section 11346.7.

DHS RESPONSE (9.j.): The Department is amending this regulation in compliance with State and federal requirements at Title 22, CCR, Sections 51513, 51513.2 and 59999(a), and 42 C.F.R. sections 447.331 and 447.332 which regulate payment limits for pharmaceutical products under the Medicaid program and which do not authorize rates which vary with the provider's size. In fact, 42 C.F.R. section 447.301 defines estimated acquisition as the agency's best estimate of the price generally paid by providers. The law does not require reimbursement to be based on the size of the provider's business; the administrative effort required to set varying rates would be excessively burdensome for the 6,000 pharmacy providers in California. No posthearing change to this regulation is required as a result of this comment.

The Department must consider the Small Business Regulatory Act in response to Section 9.d.

DHS RESPONSE (9.d.): The Department has complied with applicable laws and regulations in the adoption of this regulation. The Department knows of no law which would require a change in this regulation; therefore, no posthearing change is required as a result of this comment. See responses 1b, 2a, 2c, 3b, and Statewide Survey of Pharmacy Practices-Attachment D, Associated News article-Attachment G, and Pharmacists' Payment Data-1987/88-Attachment H in the rulemaking file.

D. The Department has not directly and fully responded to comments in Section 10.h.

DHS RESPONSE (10.h.): The Department's analysis of paid claims data found this statement to be inaccurate. An analysis of existing elements of Medi-Cal drug reimbursement, such as the FAC, MAIC and direct price,

determined that when combined with AWP-5%, they resulted in an overall discount which was equal to the Department's best estimate of the price generally and currently paid by pharmacy providers. The federal government also has determined that a discount from AWP is required. Please see 2d. The Department has determined that no posthearing change is required as a result of this comment.

3. The rulemaking file fails to include all documents relied on by the Department, and therefore fails to meet the requirements of Government Code section 11347.3, subdivision (a) (7).

DHS RESPONSE: In response to concerns from the Office of Administrative Law, the Department has submitted additional data. The rulemaking file now contains the following documents:

Attachments B, D, and E were available in the original rulemaking file:

- o November 9, 1988 letter from John O'Hara as Attachment B
- o Statewide Survey of Pharmacy Practices as Attachment D
- o Paid Claims/Savings Data-1989 as Attachment E

Attachments A, C, F, G, H, I, and J have been added to the rulemaking file and are now made available for public review.

- o Governor's 1989/90 Budget Exception Language as Attachment A
- o State Medicaid Manual as Attachment C
- o July 19, 1989 Letter from Lawrence L. McDonough as Attachment F
- o Associated News Article as Attachment G
- o Pharmacists' Payment Data 1987/88 as Attachment H.
- o Transmittal Notice From Region IV as Attachment I
- o September 22, 1989 Letter to Lawrence L. McDonough as Attachment J

4. The rulemaking file fails to demonstrate that all documents and data relied on for the proposed regulation were made available for public review.

DHS RESPONSE: The Department has made additional documents and data identified item number 3, available for public review.

Additional Problems And Concerns

1. The Office of Administrative Law expressed concern regarding the format of citations relating to the United States Code.

DHS RESPONSE: Following the guidelines presented by the Office of Administrative Law, the Department has amended the format for United States Code citations in the reference section of the regulation text to meet the required standard.

2. The Office of Administrative Law expressed concern regarding the format of citations relating to the Code of Federal Regulations.

DHS RESPONSE: Following the guidelines presented by the Office of Administrative Law, the Department has amended the format for Code of Federal Regulations citations in the reference section of the regulation text to meet the required standard.

3. The Office of Administrative Law comments that the "Alternative Considered" determination in the Final Statement of Reasons should be corrected.

DHS RESPONSE: Following the guidelines presented by the Office of Administrative Law, the Department has amended this section to read as follows:

The Department has determined that no alternatives considered would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the adopted regulation.